



Authorization and appeals kit

nr-axSpA

non-radiographic axial spondyloarthritis

Resources for healthcare providers

INDICATIONS

COSENTYX® is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

COSENTYX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

[Click here](#) for additional Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).

Information and sample letters to help ensure that your communications with health plans are as complete as possible.

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.



Cosentyx[®]
(secukinumab)

Click on number or title to jump to that section.

This kit provides you with information and sample letters that can help ensure your communications with health plans regarding a prior authorization or appeal are as complete as possible. These samples are intended to provide you with examples of the type of information that will be required. Click the  icon at the bottom of each sample letter to open an editable Word version of the letter. You can refer to the checklist on the first page of each section as you develop and complete your own letters. The more completely and accurately that you meet a plan's requirements for prescribing COSENTYX®, the more quickly you will be able to help your patients receive therapy.

Physician Letters

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Many plans require prior authorization for biologics and will have PA forms available on their websites. 3
If a prior authorization or formulary exception request is denied, you can submit an appeal.
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If an initial appeal is rejected: There can be multiple levels of appeal. Each of the appeal letters can be adapted for higher level appeals. After a second-level appeal, additional adjudication may include review by an independent noninsurance-affiliated external review board or hearing. Please refer to the plan's specific appeals guidelines, which are often available on their website.

If there is a denial after multiple levels of appeal: In line with your standard office practice, you may refer the patient to charitable foundation programs to explore eligibility for financial assistance.

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ICD-10=
International
Classification of
Diseases, Tenth
Revision;
NDC=National
Drug Code.

[Click here](#) for Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).



Suggestions for writing a Prior Authorization Request Letter*

Many plans require prior authorization (PA) for biologics and will have their own PA forms available on their websites. This section provides general guidance on submitting a PA form and provides sample letters.

Click the  icon at the bottom of each sample letter to open an editable Word version of the letter.

Tips

All COSENTYX® PA forms should be completed and submitted to the plan by your office.

Your Field Reimbursement Manager (FRM) may be able to provide you with PA requirements for specific plans and pharmacy benefit managers (PBMs). Benefits verifications performed by COSENTYX Connect Support Program and specialty pharmacies can also identify prior authorization requirements, step therapies, and form requirements.

Fax the prior authorization request to the health plan.

Fax the service request form (SRF) to the COSENTYX Connect Support Program at [1-844-666-1366](tel:1-844-666-1366).

Many specialty pharmacies have the ability to submit a test claim to a payer to confirm coverage of COSENTYX.

If the physician anticipates that a step therapy specified by the plan will not be well tolerated by the patient, an appeal to bypass that requirement may be submitted to the payer. That appeal should generally include a Letter of Medical Necessity.

[Click here](#) for a sample Letter of Medical Necessity.

Many payers will allow up to three levels of appeal of prior authorization denials. The third level of appeal may include review by an independent noninsurance-affiliated external review board or hearing. [Click here](#) for a sample Prior Authorization Appeals Letter.

Note: Some plans may require the use of their own letter templates for prior authorization requests.

Checklist

- Include the patient's name, policy number, and date of birth
- Confirm and document that all PA requirements of the plan have been met
- Confirm and document that the patient has satisfied any step-therapy requirements
- Review suggested letter formats that follow for additional guidance
- Refer to the health plan's website to locate their PA form. Your FRM may also be able to assist you

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See sample letters on following pages.

[Click here](#) for Important Safety Information.

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Sample prior authorization request letter

when patient is **not** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Patient Name]

[Policy Number]

[DOB]

To whom it may concern:

This letter is being submitted for the prior authorization of COSENTYX for [patient name, ID, and group number], for the treatment of nr-axSpA [ICD-10 Dx code].

If appealing a step edit requirement, consider inserting an explanation like that shown in the pink shaded box to detail why step therapies are not appropriate for this patient.

The plan currently requires a trial of the following therapies before COSENTYX is prescribed: [insert required step therapies]. Included, please find a statement explaining why these step therapies are not feasible. We request that the step therapy requirement be eliminated.

Patient's history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX.

Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records indicating the patient's diagnosis and date of diagnosis
- Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Composite assessment, including other features supporting diagnosis of nr-axSpA
- Documentation that you have excluded other diagnoses
- Comprehensive list of previous therapies and their duration
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

CRP=C-reactive protein;
ESR=erythrocyte sedimentation rate;
HLA=human leukocyte antigen;
MRI=magnetic resonance imaging;
NPI=national provider identifier;
nr-axSpA= non-radiographic axial spondyloarthritis.

Supporting references:

(Provide clinical support for your recommendation. This can be clinical trial data from the COSENTYX package insert.)

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to [patient name].

Sincerely,

[Physician name and signature]

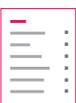
[Name of practice]

[Phone #]

Encl: Medical records
COSENTYX clinical trial data



Double-click to open a Word version of this letter.



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Sample prior authorization request letter

when patient **is** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Patient Name]

[Policy Number]

[DOB]

To whom it may concern:

This letter is being submitted for the prior authorization of COSENTYX on behalf of [patient name, ID, and group number], for the treatment of nr-axSpA [ICD-10 Dx code]. The authorization requested is for the current date of [insert date] through the date of [insert future date].

(Include information outlining the severity of nr-axSpA symptoms **at the time of COSENTYX prescription**. Historical medical records may need to be pulled to capture the information relevant to COSENTYX treatment at an earlier date.)

If appealing a step edit requirement, consider inserting an explanation like that shown in the pink shaded box to detail why step therapies are not appropriate for this patient.

The plan currently requires a trial of the following therapies before COSENTYX is prescribed: [insert required step therapies]. Included, please find a statement explaining why these step therapies are not feasible. We request that the step therapy requirement be eliminated.

Patient's history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX.

Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records indicating the patient's diagnosis and date of diagnosis
- Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Composite assessment, including other features supporting diagnosis of nr-axSpA
- Documentation that you have excluded other diagnoses
- Comprehensive list of previous therapies and their duration
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

CRP=C-reactive protein;
ESR=erythrocyte sedimentation rate;
HLA=human leukocyte antigen;
MRI=magnetic resonance imaging;
NPI=national provider identifier;
nr-axSpA= non-radiographic axial spondyloarthritis.

Supporting references:

(Provide clinical support for your recommendation. This can be clinical trial data from the COSENTYX package insert.)

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to [patient name].

Sincerely,

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records
COSENTYX clinical trial data



Double-click to open a Word version of this letter.



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Suggestions for writing a Prior Authorization Appeals Letter*

This type of letter can be used when a prior authorization request has been denied. There can be multiple levels of appeal. Please refer to the plan's specific appeals guidelines.

This letter comes from the **physician**. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity.

[Click here for a sample Letter of Medical Necessity.](#)

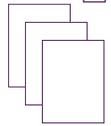
Click the  icon at the bottom of each sample letter to open an editable Word version of the letter.

Checklist

- Include the patient's name, policy number, date of birth, PA denial reference number and date of denial**

- Acknowledge that you are familiar with the company's policy and state the reason for the denial**

- Patient's medical records**



Patient history, diagnosis, current condition, and symptoms

Include copies of relevant medical records (payers may want to see if any infections, allergies, or comorbidities are present)



A description of MRI evidence

- Describe severity of condition**

- List previous therapies**

Explain why each therapy was discontinued, and specify the duration of therapy for each agent

- Explain why formulary preferred agents are not appropriate**
(if they have not already been listed as previous therapies)

- Provide clinical support for your recommendation**
This can be clinical trial data from the COSENTYX® package insert.

- If required, attach a **Letter of Medical Necessity**
[Click here for a sample Letter of Medical Necessity.](#)

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

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See sample letters on following pages.



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Sample prior authorization appeals letter when patient is **not** already taking COSENTYX® (secukinumab)

[Today's Date]
 [Medical Director]
 [Insurance Company]
 [Address]

Re: [Patient Name]
 [Policy Number]
 [DOB]
 [PA Denial Reference # and Date]

To whom it may concern:

I have read and acknowledge your policy for the responsible management of drugs in this category.

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded pink box.

This is a [Insert level of request] prior authorization appeal. A copy of the most recent denial letter is included along with medical notes in response to the denial.

I am writing to request that you reconsider your denial of coverage of COSENTYX for the treatment of nr-axSpA [ICD-10 Dx code]. The reason given for the denial was [state reason from insurer's letter]. After reviewing the denial letter, I maintain that COSENTYX [dose, frequency] is the appropriate therapy. Listed below is a summary of the relevant clinical history.

Patient's history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX.

Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records indicating the patient's diagnosis and date of diagnosis
- Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Composite assessment, including other features supporting diagnosis of nr-axSpA
- Documentation that you have excluded other diagnoses
- Comprehensive list of previous therapies and their duration
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

CRP=C-reactive protein;
 ESR=erythrocyte sedimentation rate;
 HLA=human leukocyte antigen;
 MRI=magnetic resonance imaging;
 nr-axSpA= non-radiographic axial spondyloarthritis.

Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

 [Physician name and signature]
 [Name of practice]
 [Phone #]

Encl: Medical records
 Letter of denial
 COSENTYX clinical trial data



Double-click to open a Word version of this letter.



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Sample prior authorization appeals letter

when patient **is** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Patient Name]

[Policy Number]

[DOB]

[PA Denial Reference # and Date]

To whom it may concern:

I have read and acknowledge your policy for the responsible management of drugs in this category.

If this is a 2nd- or 3rd-level appeal, consider including an explanation like the one in the shaded pink box.

This is a [Insert level of request] prior authorization appeal. A copy of the most recent denial letter is included along with medical notes in response to the denial.

I am writing to request that you reconsider your denial of coverage of COSENTYX for the treatment of nr-axSpA [ICD-10 Dx code]. The reason given for the denial was [state reason from insurer's letter]. After reviewing the denial letter, I maintain that COSENTYX [dose, frequency] is the appropriate therapy. Listed below is a summary of the relevant clinical history.

(Include information outlining the severity of the patient's symptoms **at the time of COSENTYX prescription**. Historical medical records may need to be pulled to capture the information relevant to COSENTYX treatment at an earlier date.)

Patient's history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX.

Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records indicating the patient's diagnosis and date of diagnosis
- Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Composite assessment, including other features supporting diagnosis of nr-axSpA
- Documentation that you have excluded other diagnoses
- Comprehensive list of previous therapies and their duration
- Confirmation that the patient has not received adequate results from previous treatments
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ESR=erythrocyte sedimentation rate;
HLA=human leukocyte antigen;
MRI=magnetic resonance imaging;
nr-axSpA= non-radiographic axial spondyloarthritis.

Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records

Letter of denial

COSENTYX clinical trial data



Double-click to open a Word version of this letter.



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Suggestions for writing a Letter of Medical Necessity*

Some plans require that a Letter of Medical Necessity be submitted along with a Prior Authorization Appeal to support the choice of COSENTYX® over agents that are on formulary.

[Click here](#) for a sample Prior Authorization Appeals Letter.

Click the  icon at the bottom of each sample letter to open an editable Word version of the letter.

You may find that this checklist and the sample letters that follow are a helpful guide to preparing that letter. A Letter of Medical Necessity should also accompany a Formulary Exception Request Letter as well as a Tiering Exception Request Letter.

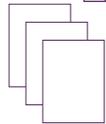
[Click here](#) for a sample Formulary Exception Request Letter.

[Click here](#) for a sample Tiering Exception Request Letter.

Checklist

- Include the patient's name, policy number, date of birth, and, if appropriate, PA denial reference number and date of denial**

- Support your recommendation with the following:**



Patient history, diagnosis, current condition, and symptoms

Include copies of relevant medical records (payers may want to see if any infections, allergies, or comorbidities are present)



A description of MRI evidence

- Describe severity of condition**

- List previous therapies**

Explain why each therapy was discontinued, and specify the duration of therapy for each agent

- Explain why formulary preferred agents are not appropriate**
(if they have not already been listed as previous therapy)

- Provide clinical support for your recommendation**
This can be clinical trial data from the COSENTYX package insert

- To close the letter, summarize your recommendation, and provide a phone number should any additional information be required**

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See sample letters on following pages.



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Sample letter of medical necessity

when patient is **not** already taking COSENTYX® (secukinumab)

[Today's Date]
[Medical Director]
[Insurance Company]
[Address]

Re: [Patient Name]
[Policy Number]
[DOB]
[Optional: PA Denial Reference # and Date]

To whom it may concern:

I am writing on behalf of my patient, [patient name], to support the coverage of COSENTYX for the treatment of nr-axSpA [ICD-10 Dx code]. I have read and acknowledge your policy for the responsible management of drugs in this category. In this letter, I provide my rationale for the use of COSENTYX [dose, frequency] and explain why, in my clinical judgement, it is required for the appropriate management of this patient. I have also included a brief description of the patient's medical history and a review of previous therapies.

Patient's history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records indicating the patient's diagnosis and date of diagnosis
- Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Composite assessment, including other features supporting diagnosis of nr-axSpA
- Documentation that you have excluded other diagnoses
- Comprehensive list of previous therapies and their duration
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

CRP=C-reactive protein;
ESR=erythrocyte sedimentation rate;
HLA=human leukocyte antigen;
MRI=magnetic resonance imaging;
nr-axSpA= non-radiographic axial spondyloarthritis.

Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

[Physician name and signature]
[Name of practice]
[Phone #]

Encl: Medical records
COSENTYX clinical trial data



Double-click to open a Word version of this letter.



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Sample letter of medical necessity

when patient **is** already taking COSENTYX® (secukinumab)

[Today's Date]
 [Medical Director]
 [Insurance Company]
 [Address]

Re: [Patient Name]
 [Policy Number]
 [DOB]
 [Optional: PA Denial Reference # and Date]

To whom it may concern:

I am writing on behalf of my patient, [patient name], to support the coverage of COSENTYX for the treatment of nr-axSpA [ICD-10 Dx code]. I have read and acknowledge your policy for the responsible management of drugs in this category. In this letter, I provide my rationale for the use of COSENTYX [dose, frequency] and explain why, in my clinical judgement, it is required for the appropriate management of this patient. I have also included a brief description of the patient's medical history and a review of previous therapies.

(Include information outlining the severity of the disease and the patient's symptoms **at the time of COSENTYX prescription**. Historical medical records may need to be pulled to capture the information relevant to COSENTYX treatment at an earlier date.)

Patient's history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your diagnosis and reason for treatment with COSENTYX. Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records indicating the patient's diagnosis and date of diagnosis
- Description of patient's symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Composite assessment, including other features supporting diagnosis of nr-axSpA
- Documentation that you have excluded other diagnoses
- Comprehensive list of previous therapies and their duration
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting COSENTYX
- Impact on quality of life
- Summary of recommendation]

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 ESR=erythrocyte sedimentation rate;
 HLA=human leukocyte antigen;
 MRI=magnetic resonance imaging;
 nr-axSpA= non-radiographic axial spondyloarthritis.

Please contact my office by calling [insert phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

 [Physician name and signature]
 [Name of practice]
 [Phone #]

Encl: Medical records
 COSENTYX clinical trial data

 Double-click to open a Word version of this letter.



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Suggestions for writing a Formulary Exception Request Letter*

This type of letter can be used when COSENTYX® is not listed on a formulary or if it has an NDC block. While the plan may provide a form on its website that can be used to apply for an exception, you can refer to the sample provided in this kit to see the type of information that is typically required.

Click the  icon at the bottom of each sample letter to open an editable Word version of the letter.

This letter comes from the **patient** and is also signed by the **physician**. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity.

[Click here](#) for a sample Letter of Medical Necessity.

Checklist

- Include your name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial**
- Your diagnosis**
- List of your previous therapies**
- The main reasons that support your request for a formulary exception for COSENTYX**
- Relevant medical records**
- If this is a 2nd-level or 3rd-level appeal**, include the letter of denial and your physician's medical notes in response to the denial
- If required, attach a **Letter of Medical Necessity** from your physician
[Click here](#) for a sample Letter of Medical Necessity.

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

NDC=National Drug Code.

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See sample letters on following pages.

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Please see full [Prescribing Information](#), including [Medication Guide](#).



Sample formulary exception request letter

when you are **not** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Name]

[Policy Number]

[DOB]

[Optional: Denial Reference # and Date]

To whom it may concern:

I am a member of [enter name of health plan]. Currently, COSENTYX is not listed on my formulary, and according to my doctor, my medical condition necessitates the use of this drug.

If this is a 2nd- or 3rd- level appeal, consider including an explanation like the one in the shaded purple box. Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

This is my [Insert level of request] formulary exception appeal. A copy of the original denial letter is included along with medical notes in response to the denial.

I am requesting an exception to your formulary so that I am able to fill my prescription for COSENTYX. I request that it be available to me as a preferred drug and that any applicable NDC blocks be removed.

I have been diagnosed with nr-axSpA and my doctor has prescribed COSENTYX [strength]. Dr. [insert physician name], [insert medical specialty], practices at [insert physician address]. My past treatments have included [list previous treatments and drugs]. I have enclosed my medical records and a letter of medical necessity from my physician supporting my request for the formulary exception approval of COSENTYX.

The main reasons that I am requesting this exception are:

[Insert main medical necessity points]

These reasons are supported by the information that I have included. My physician can be contacted at [insert phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of COSENTYX in the treatment of my medical condition.

Sincerely,

Be sure to have your physician sign the letter.

Enclose your medical records along with a letter of medical necessity from your physician.

[Patient name and signature]

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records
Letter of medical necessity



Double-click to open a Word version of this letter.



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Sample formulary exception request letter

when you **are** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Name]

[Policy Number]

[DOB]

[Optional: Denial Reference # and Date]

To whom it may concern:

I am a member of [enter name of health plan]. Currently COSENTYX is not listed on my formulary, and according to my doctor, my medical condition necessitates the use of this drug.

If this is a 2nd- or 3rd- level appeal, consider including an explanation like the one in the shaded purple box. Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

This is my [Insert level of request] formulary exception appeal. A copy of the original denial letter is included along with medical notes in response to the denial.

I am requesting an exception to your formulary so that I am able to fill my prescription for COSENTYX. I request that it be available to me as a preferred drug and that any applicable NDC blocks be removed.

I have been diagnosed with nr-axSpA and my doctor has prescribed COSENTYX [strength]. Dr. [insert physician name], [insert medical specialty], practices at [insert physician address]. My past treatments have included [list previous treatments and drugs]. I have enclosed my medical records and a letter of medical necessity from my physician supporting my request for the formulary exception approval of COSENTYX. (Note: medical records should include the records from the date COSENTYX was first prescribed to the patient and should also include disease severity indicators.)

The main reasons that I am requesting this exemption are:

[Insert main medical necessity points]

These reasons are supported by the information that I have included. My physician can be contacted at [insert phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of COSENTYX in the treatment of my medical condition.

Sincerely,

NDC=National Drug Code.; nr-axSpA= non-radiographic axial spondyloarthritis.

Be sure to have your physician sign the letter.

Enclose your medical records along with a letter of medical necessity from your physician.

[Patient name and signature]

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records
Letter of medical necessity



Double-click to open a Word version of this letter.



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Please see full [Prescribing Information](#), including [Medication Guide](#).

Suggestions for writing a Tiering Exception Request Letter*

This type of letter can be used when COSENTYX® is on formulary but is on a tier with a high co-pay. Based on medical necessity, you can appeal to the plan to consider the drug as if it were a preferred branded agent in order to reduce the out-of-pocket expense and help alleviate the financial burden. This may be most useful for patients on plans that require coinsurance. This letter comes from the **patient** and is also signed by the **physician**.

Click the  icon at the bottom of each sample letter to open an editable Word version of the letter.

Checklist

- Include your name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial
- Your diagnosis
- Include a statement of financial hardship
- List your previous therapies
- Relevant medical records
- If this is a **2nd-level or 3rd-level appeal**, include the letter of denial and your physician's medical notes in response to the denial
- If required, attach a **Letter of Medical Necessity** from your physician
[Click here](#) for a sample Letter of Medical Necessity.

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

*The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

See sample letters on following pages.

[Click here](#) for Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).



Sample tiering exception request letter

when you are **not** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Name]

[Policy Number]

[DOB]

[Optional: Denial Reference # and Date]

To whom it may concern:

I am requesting a tier exception for the drug COSENTYX prescribed to me by [insert physician name and specialty] for the diagnosis of nr-axSpA. [If your prior insurance covered COSENTYX on a preferred tier, describe this previous coverage.]

If this is a 2nd- or 3rd- level appeal, consider including an explanation like the one in the shaded purple box.

Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

This is my [Insert level of request] tier exception appeal. A copy of the original tier exception denial letter is included along with medical notes in response to the denial.

COSENTYX is delivered by subcutaneous injection at a dose of [insert strength of drug]. The initial requested length of tier exception approval is for [insert requested length of initial approval].

I have attached medical records and a letter of medical necessity from my physician outlining why COSENTYX is needed for my medical care over other drugs listed as preferred on my formulary. [Describe why low-tiered formulary drugs would not be as effective.] Past treatments and drugs that have been unsuccessful in achieving control of my symptoms include [insert list of past treatments and drugs]. My current symptoms are [insert complete list of symptoms].

My current treatment is [list current treatments]. I am requesting a tier exception because the current assigned tier for COSENTYX would be a burden on my finances and would hinder my ability to utilize a drug that will assist with the treatment of my diagnosis.

In summary, my physician believes that COSENTYX is the best choice for my health and treatment of nr-axSpA. My physician may be reached to answer any additional questions or to participate in a peer-to-peer review by calling [insert physician's phone number].

Sincerely,

[Patient name and signature]

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records
Letter of medical necessity

Be sure to have your physician sign the letter.

Enclose your medical records along with a letter of medical necessity from your physician.



Double-click to open a Word version of this letter.



[Click here for Important Safety Information.](#)

Please see full [Prescribing Information](#), including [Medication Guide](#).

Sample tiering exception request letter

when you **are** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Name]

[Policy Number]

[DOB]

[Optional: Denial Reference # and Date]

To whom it may concern:

I am requesting a tier exception for the drug COSENTYX prescribed to me by [insert physician name and specialty] for the diagnosis of nr-axSpA. [If prior insurance covered COSENTYX on a preferred tier, describe this previous coverage.]

If this is a 2nd- or 3rd- level appeal, consider including an explanation like the one in the shaded purple box. Be sure to include a copy of the original letter of denial along with your doctor's specific medical notes in response to the denial.

This is my [Insert level of request] tier exception appeal. A copy of the original tier exception denial letter is included along with medical notes in response to the denial.

COSENTYX is delivered by subcutaneous injection at a dose of [insert strength of drug]. The initial requested length of tier exception approval is for [insert requested length of initial approval].

I have attached medical records and a letter of medical necessity from my physician outlining why COSENTYX is needed for my medical care over other drugs listed as preferred on my formulary. **[Insert copies of medical records dating to the initial prescription of COSENTYX.]** [Insert a summary of reason(s) why low-tiered formulary drugs would not be as effective.] Past treatments and drugs that have been unsuccessful in achieving control of my symptoms include [insert list of past treatments and drugs.]

The difference in my health status after [insert length of time] of COSENTYX therapy compared with my status before starting COSENTYX confirms that COSENTYX is medically necessary for treating my condition. [Insert specifics on improvements in symptoms since taking COSENTYX].

I am requesting a tier exception because I am not able to afford the [select co-pay or coinsurance] for COSENTYX without financial relief.

In summary, my physician believes that COSENTYX is the best choice for my health and treatment of nr-axSpA. My physician may be reached to answer any additional questions or to participate in a peer-to-peer review by calling [insert physician's phone number].

Sincerely,

[Patient name and signature]

[Physician name and signature]

[Name of practice]

[Phone #]

Encl: Medical records
Letter of medical necessity

nr-axSpA=
non-radiographic
axial spondylo-
arthritis.

Be sure to have
your physician
sign the letter.

Enclose your
medical records
along with a letter
of medical
necessity from
your physician.



Double-click
to open a Word
version of this
letter.



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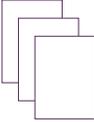
Please see full [Prescribing Information](#), including [Medication Guide](#).

Suggestions for writing a Dosage Appeals Letter*

Some plans may not approve loading doses of COSENTYX® for nr-axSpA unless an appeal is submitted by the patient. This section provides general guidance on submitting an appeal for an alternate dosing regimen. This letter comes from the **patient** and is also signed by the **physician**.

Click the  icon at the bottom of each sample letter to open an editable Word version of the letter.

Checklist

- Include your name, policy number, date of birth, and, if appropriate, the denial reference number from a previous appeal and the date of denial**
- Your diagnosis**
- Explain why you are requesting approval to initiate therapy with a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4**
- Support your recommendation with the following:**
 -  Your patient history, diagnosis, current condition, and symptoms
 - Include copies of relevant medical records that your physician can provide (payers may want to see if any infections, allergies, or comorbidities are present)
- Describe the severity of your condition**
- Ask your physician to provide clinical support for this request**
- To close the letter, summarize the recommendation from your physician and provide a phone number should any additional information be required**
- If required, attach a **Letter of Medical Necessity**
[Click here](#) for a sample Letter of Medical Necessity.

nr-axSpA=
non-radiographic
axial spondylo-
arthritis.

Note: At each stage of appeal, health plans may require that their own forms (or the universal forms that are required by some states) be submitted along with your letter.

*The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

See sample letters on following pages.

[Click here](#) for Important Safety Information.

Please see full [Prescribing Information](#), including [Medication Guide](#).



Sample loading dose appeals letter

when you are **not** already taking COSENTYX® (secukinumab)

[Today's Date]

[Medical Director]

[Insurance Company]

[Address]

Re: [Name]

[Policy Number]

[DOB]

[Optional: Denial Reference # and Date]

To whom it may concern:

I am a member of [enter name of health plan]. I have been approved for initiation of COSENTYX without a loading dose. According to my doctor, my condition warrants initiation with a loading dose.

This letter is being submitted for approval to initiate COSENTYX for the treatment of nr-axSpA with a 5-week loading dose: 150 mg at weeks 0, 1, 2, 3, and 4.

[Describe any experience of nocturnal awakenings due to this condition. If your pain and stiffness improve with movement, describe that. Discuss the impact on your overall quality of life.]

My physician has provided my patient history, diagnosis, current condition, and symptoms

[Include relevant medical information to support your request.

Examples of information you may want to include are:

- Tuberculosis test and results
- Medical records describing my diagnosis and the date of diagnosis
- Description of my symptoms such as nocturnal awakenings or continuous chronic back pain with age of onset before age 45 with pain and stiffness that improve with movement
- Test results such as: HLA-B27, CRP, or ESR
- A description of MRI evidence
- Your physician's composite assessment supporting the diagnosis of nr-axSpA
- Comprehensive list of previous treatment therapies
- Rationale for initiating COSENTYX with a loading dose: 150 mg at weeks 0, 1, 2, 3, and 4]

[Insert physician's clinical support.]

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician business office address]. Please also send a copy of the coverage determination decision to me.

Sincerely,

[Patient name and signature]

[Physician name and signature]

[Name of practice]

[Phone #]

CRP=C-reactive protein;
ESR=erythrocyte sedimentation rate; HLA=human leukocyte antigen; MRI=magnetic resonance imaging; NPI=national provider identifier; nr-axSpA= non-radiographic axial spondyloarthritis.

Be sure to have your physician sign the letter.

Enclose your medical records along with a letter of medical necessity from your physician.

 Double-click to open a Word version of this letter.

Encl: Medical records
Letter of medical necessity



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Examples of relevant *ICD-10* codes* for COSENTYX® (secukinumab) patients

The following *ICD-10 CM* codes for nr-axSpA are included in the 2021 *ICD-10-CM* Index of Diseases and Injuries, which goes into effect on October 1, 2020.¹

Possible <i>ICD-10-CM</i> Codes	Descriptor
M46.80	Non-radiographic axial spondyloarthritis
M46.82	Non-radiographic axial spondyloarthritis of cervical region
M46.83	Non-radiographic axial spondyloarthritis of cervicothoracic region
M46.84	Non-radiographic axial spondyloarthritis of lumbar region
M46.84	Non-radiographic axial spondyloarthritis of thoracic region
M46.85	Non-radiographic axial spondyloarthritis of thoracolumbar region
M46.87	Non-radiographic axial spondyloarthritis of lumbosacral region
M46.88	Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region
M46.89	Non-radiographic axial spondyloarthritis of multiple sites

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

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Reference: 1. International Classification of Diseases, Tenth Revision, Clinical Modification (*ICD-10-CM*). Centers for Disease Control and Prevention website. 2021 *ICD-10-CM* Index of Diseases and Injuries. Accessed July 27, 2020. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2021/



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COSENTYX® (secukinumab) Connect Support Program

A personal support program that provided resources to the practice and patient to help patients get started on COSENTYX.

Dosage Appeals Letter

Some plans may not approve all dosing options that are included on the drug's label. A dosage appeal letter can be used to request approval for a starting dose that is a higher or more frequent dose than the plan has approved.

Formulary

List of prescription drugs that are covered by a health plan.

Formulary Exception Request Letter

This type of letter can be sent by the patient to request that a drug, not currently included on the plan's formulary, be approved for the patient.

Letter of Medical Necessity

This letter is written by a physician to present his or her clinical judgement supporting the diagnosis and the need for a specific therapy.

Prior Authorization (PA) Request Letter

Plans may require that a practice submit documentation of certain criteria before they agree to pay for a drug. A PA letter shows that the patients meets the plan's criteria. It is sent by the physician.

Prior Authorization Appeals Letter

When a prior authorization request is not approved, this type of letter can be used to appeal the decision. It may included more detailed information than what was included in the original PA request. This letter is also sent by the physician.

Tiering Exception Request Letter

When a drug is included on the plan's formulary but has a high copay or coinsurance, this type of letter can be used to appeal that they grant an exception for this patient and place the drug on a lower tier so that the patient has a lower out-of-pocket expense. This letter should be sent by the patient.

National Drug Code (NDC)

Universal product identifier with a unique set of numbers used for human drugs in the United States.

Pharmacy Benefits Manager (PBM)

Organizations that administer prescription drug plans on behalf of health insurers and employers.



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INDICATIONS

COSENTYX® is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

COSENTYX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections

COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in subjects treated with COSENTYX compared to placebo-treated subjects. In placebo-controlled clinical trials in patients with moderate to severe plaque psoriasis, higher rates of common infections such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%), and mucocutaneous infections with candida (1.2% versus 0.3%) were observed with COSENTYX compared with placebo. A similar increase in risk of infection was seen in placebo-controlled trials in patients with psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. The incidence of some types of infections appeared to be dose-dependent in clinical studies.

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and COSENTYX should be discontinued until the infection resolves.

Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Do not administer COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving COSENTYX should be monitored closely for signs and symptoms of active TB during and after treatment.

Please see additional Important Safety Information on page 23.



[Click here for Important Safety Information.](#)

Please see full [Prescribing Information](#), including [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (cont)**WARNINGS AND PRECAUTIONS (cont)****Inflammatory Bowel Disease**

Caution should be used when prescribing COSENTYX® (secukinumab) to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in patients treated with COSENTYX during clinical trials in plaque psoriasis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory study in 59 patients with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease.

Hypersensitivity Reactions

Anaphylaxis and cases of urticaria occurred in patients treated with COSENTYX in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated.

The removable cap of the COSENTYX Sensoready® pen and the COSENTYX prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

Vaccinations

Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with COSENTYX should not receive live vaccines.

Non-live vaccinations received during a course of COSENTYX may not elicit an immune response sufficient to prevent disease.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

Please see additional Important Safety Information on page 22.

Reference:

Cosentyx [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2020.

www.cosentyx.com



[Click here for Important Safety Information.](#)

Please see full [Prescribing Information](#), including [Medication Guide](#).

COSENTYX® Connect

You or your patient can call

1-844-267-3689

8:00 AM to 9:00 PM Eastern Time, Monday through Friday, excluding public holidays.

Fax

1-844-666-1366

For additional information, go to

www.cosentyx.com



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